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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/631,275

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Mark T. Richardson

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FULWIDER PATTON LLP
HOWARD HUGHES CENTER
6060 CENTER DRIVE, TENTH FLOOR
LOS ANGELES, CA 90045

EXAMINER

LLOYD, EMILY M

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/17/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/631,275	Applicant(s) RICHARDSON ET AL.	
	Examiner Emily M. Lloyd	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-39 and 59-85 is/are pending in the application.
- 4a) Of the above claim(s) 34,35 and 59-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-33,36 and 37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/08/2003</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I and Species A (claims 24-33 and 36-37) in the reply filed on 26 March 2007 is acknowledged.
2. Claims 34-35 and 59-85 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 26 March 2007.

Information Disclosure Statement

3. The information disclosure statement filed 8 September 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

4. The drawings are objected to because the component 225 labeled closest to the "FIG. 26" label appears to be pointing to something other than the object the 225 label above it (between the 203 and 221 labels) point to. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing

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should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 89, 121A, 122A, 122B, 122C, 123A, 123B, 212, 314A, 315A, 435, and 456. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 476. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

7. The disclosure is objected to because of the following informalities: Page 7 line 13 is missing the numerical values that represent the measurement in mm; Page 10 line 8, Page 25 lines 2, 8, and 13, and Page 26 line 5 should say "finished" or "final" instead of "finish"; Page 18 line 12 should refer to circle 40B instead of circle 2B; Page 19 line 20 should refer to "distal core section 13" instead of "distal core section 12"; Page 20 lines 9-10 refer to guidewire 10 in Figure 4 but there is not a reference number 10 in Figure 4; Page 28 line 1 refers to component 74 as "midpoints" but only one is shown in the figures; Page 54 line 5 should refer to element 246 instead of 24; Page 55 line 11 should refer to element 260 instead of 230; Page 59 line 3 should use the word "of"

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instead of "at"; Page 59 line 14 and Page 60 lines 10 and 12 should refer to element 311 instead of 111; Page 60 line 9 should refer to element 313 instead of 113; Page 67 line 20 the phrase "so that as" should be revised to fit grammatically with the rest of the sentence; Page 71 line 13 the reference to Figure 46 should instead cite Figure 47; and Page 75 line 15 is missing the word "are" between "523" and "inserted".

Appropriate correction is required.

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24-33 and 36-37 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2, 23, 27-33, and 37-41 of U.S. Patent No. 6673025. Claim 24 is rejected on the basis of claims 23 and 29 of Patent 6673025, where the flexible body member is a helical coil (claim 23 line 6) and the plurality of radiopaque markers are the helical coil's "plurality of spaced portions separated by adjacent non-spaced portions with the spaced portions having less radiopacity than adjacent non-spaced portions and being spaced at regular predetermined longitudinal positions" (claim 23 lines 8-12). Claim 25 is rejected on the basis of claim 30 of Patent 6673025. Claim 26 is rejected on the basis of claim 2 of Patent 6673025. While claim 26 depends on another claim not referenced here, it would have been obvious to combine a feature claimed in Patent 6673025 with other claimed embodiments of the same patent. Claim 27 is rejected on the basis of claim 28 of Patent 6673025. Claim 28 is rejected on the basis of claim 27 of Patent 6673025. Claim 29 is rejected on the basis of claim 24 of Patent 6673025. Claim 30 is rejected on the basis of claim 31 of Patent 6673025. Claim 31 is rejected on the basis of claim 33 of Patent 6673025. Claim 32 is rejected on the basis of claim 32 of Patent 6673025, where the radiopaque matrix is made of the "plurality of sites at regular intervals with respect to axial position with a radiopaque material disposed on the helical coil and separated by radiolucent portions of the helical coil" (claim 32 lines 7-10). Claim 33 is rejected on the basis of claim 37 of Patent 6673025. Claim 36 is rejected on the basis of claim 41 of Patent 6673025. Claim 37 is rejected on the basis of claim 33 of Patent

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6673025. Since the claims of the instant application are "anticipated" by the claims of the patent, the claims are not patentably distinct.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 24, 26, and 30-31 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 5253653 (Daigle et al.).

Daigle et al. discloses a guidewire (fluoroscopically viewable guidewire for catheters) comprising an elongated core member (core wire 5 Figure 1) having a proximal section (larger diameter body section 5a Figure 1) and a distal section (smaller diameter section 5c Figure 1) with a plurality of radiopaque markers disposed thereon at regular intervals in axial position (markers 11 Figure 1 are a series of radiopaque rings (Column 3 line 26) and a longitudinal portion that tapers distally to a reduced transverse dimension (necked down section 5b Figure 1); a flexible body member disposed about the distal section of the elongate core member (helical coils 8 Figure 1); and a polymer layer disposed about at least a portion of the distal section of the elongate core member and the flexible body member (jacket 30 Figure 1, see also Column 3 line 62 to Column 4 line 4). Daigle et al. also discloses that the polymer layer has a substantially constant outer diameter (Figure 1 shows the outer diameter of the polymer over 5a and 5b as constant). Additionally, Daigle et al. disclose that the radiopaque markers are made of

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a radiopaque metal (Column 4 lines 8-10) secured to the distal section of the elongate core member (markers 11 Figure 1), and the radiopaque metal for the radiopaque markers is selected from the group consisting of gold, platinum, platinum-iridium, tantalum and tungsten (gold, platinum, and tantalum, Column 4 lines 8-10).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 25, 32-33, and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daigle et al. in view of United States Patent 5385152 (Abele et al.).

Daigle et al. disclose the claimed invention except for that the polymer layer is selected from a group consisting of polyurethanes, polyamide, copolymers of polyurethane and copolymers of polyamide, and that the markers are made of a radiopaque matrix applied to the distal section of the elongate core member, and that the radiopaque matrix comprises a radiolucent polymer doped with a radiopaque material, and that the radiolucent polymer comprises polyurethane and the radiopaque material comprises tungsten powder. Abele et al. teach the use of a polymer layer selected from a group consisting of polyurethanes, polyamide, copolymers of polyurethane and copolymers of polyamide (polyurethane Column 5 lines 42-43) and the markers being made of a radiopaque matrix (Column 10 lines 29-31) applied to the distal section of the elongate core member (Figures 11 and 11a, radiopaque matrix is applied to the distal end), and that the radiopaque matrix comprises a radiolucent polymer doped with a radiopaque material (Column 10 lines 29-31), and that the radiolucent polymer comprises polyurethane (polyurethane Column 5 lines 42-43) and the radiopaque material comprises tungsten powder (Column 10 line 30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a polymer layer material and radiopaque matrix applied to the distal section of the elongate core member, with the radiopaque matrix comprising a radiolucent

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polymer doped with a radiopaque material, and the radiolucent polymer comprising polyurethane and the radiopaque material comprising tungsten powder as taught by Abele et al. to provide a reference for measuring occlusions inside the human body in the invention of Daigle et al. because it is well known in the art to substitute alternative materials that perform the same function.

16. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daigle et al. in view of United States Patent 5746701 (Noone).

Daigle et al. disclose the claimed invention except for the longitudinal portion having a substantially linear change in stiffness with respect to a change in axial position. Noone teaches the use of the longitudinal portion having a substantially linear change in stiffness with respect to a change in axial position (Column 5 lines 25-35). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a longitudinal portion having a substantially linear change in stiffness with respect to a change in axial position as taught by Noone to prevent sudden changes in stiffness at points in the guidewire in the invention of Daigle et al. because this will allow for easier placement of the guidewire within the body (Noone Column 1 lines 57-65).

17. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daigle et al. in view of United States Patent 4748986 (Morrison et al.).

Daigle et al. disclose the claimed invention except for the guidewire having a longitudinal portion with a length of about 5 to about 25 cm and the longitudinal portion having a curvilinear taper. Morrison et al. teach the use of the guidewire having a

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longitudinal portion with a length of about 5 to about 25 cm ("four centimeters plus or minus 2 centimeters" Column 2 lines 45-46, this would result in a maximum of 6 cm, which is in the claimed range) and the longitudinal portion having a curvilinear taper (tapered portion 12b Figures 1 and 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a longitudinal portion with a length of about 5 to about 25 cm and having a curvilinear taper as taught by Morrison et al. in the invention of Daigle et al. because these are suitable lengths for tapered portions (Morrison et al. Column 2 lines 45-46).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
Art Unit 3736

EML


EMILY M. LLOYD
PATENT EXAMINER
ART UNIT 3736